8 Principles of Vaccine Storage

Shirelle Everett
Storage and Handling Consultant
NC Immunization Branch

DO NOT FREEZE REFRIGERATED VACCINES

Principle 1:

Vaccine Temperatures

- 35°F to 46°F (2°C to 8°C)
- Freezing can destroy refrigerated vaccine proteins.
- Freezing = 32° F or 0° C.
- Heat degrades vaccine protein over time.
  - Decay can be halted or delayed by return to proper storage temperatures
  - Out of range times are cumulative.

Vaccine Temperatures

- Sterile Diluent should never be frozen.
- Never use visual inspection to determine whether vaccine has been frozen or not.
- Always move vaccine to appropriate temperature range and call the Immunization Branch when vaccine has gone out of range.

Vaccine Temperatures

- Freezer temperature must be maintained between -50°C and -15°C (-58°F and +5°F) with an optimum of -20° C (-4°F).
- Varicella Containing vaccines and MMR are the only vaccines that should be frozen.
- Frozen vaccines die quickly when exposed to heat.
- Always call, never assume.

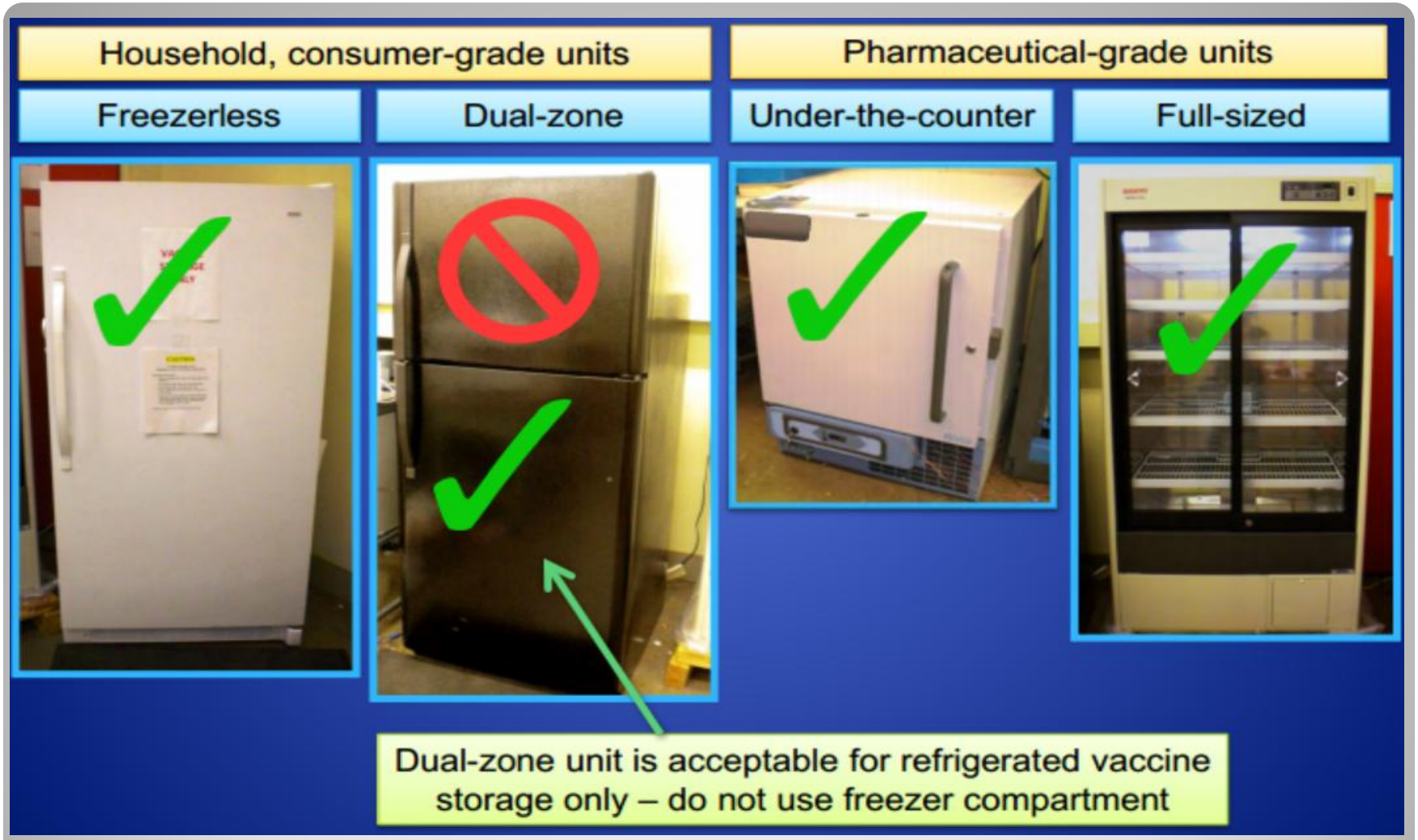
Vaccine Temperatures

- **VFC Requirements**
  - Report Incidents that require vaccine loss, the reason, and number of dose.
  - Providers must have protocols for vaccine management.

  - **Recommendation:**
  - CDC recommends that patients who received vaccine that has been deemed compromised be revaccinated.

STORE VACCINES IN EQUIPMENT THAT MAINTAINS APPROPRIATE STORAGE TEMPERATURES

Principle 2



Vaccine storage Units

Vaccine Storage Units

- *Stand Alone*:
  - Can easily maintain temperatures.
  - Storage density and packing style did not appear to have major impact on vaccine temperature.
  - In normal daily use, all thermometers remained in range.
  - No worries about freezer temperatures freezing top shelved vaccine.

Vaccine Storage

- *Dorm Style Units-*
  - No good storage locations in whole unit.
  - Ambient room temperatures affect temperature inside negatively.
  - Lack temperature control requiring frequent adjustments to set point temperatures.

Vaccine Storage Unit

- *Combination*:
  - Duel control highly recommended.
  - No vaccine on top shelves- More Water bottles.
  - If unable to keep temperatures in both compartments, use refrigerator portion and replace freezer with stand alone.

Vaccine storage Units

- *Pharmaceutical Grade*:
  - Excellent temperature stability.
  - Daily use had no effect on temperature.
  - Most usable storage space.

Vaccine Storage Units

Storage Unit Requirements

- Line units with water bottles (refrigerator) and Ice Packs (freezer).
- Unit size must be large enough to hold year's larger vaccine amounts (usually flu season).
- Tightly packed vaccines are not acceptable.
- Vaccines can be negatively affected if pre-drawn or stored outside of box.

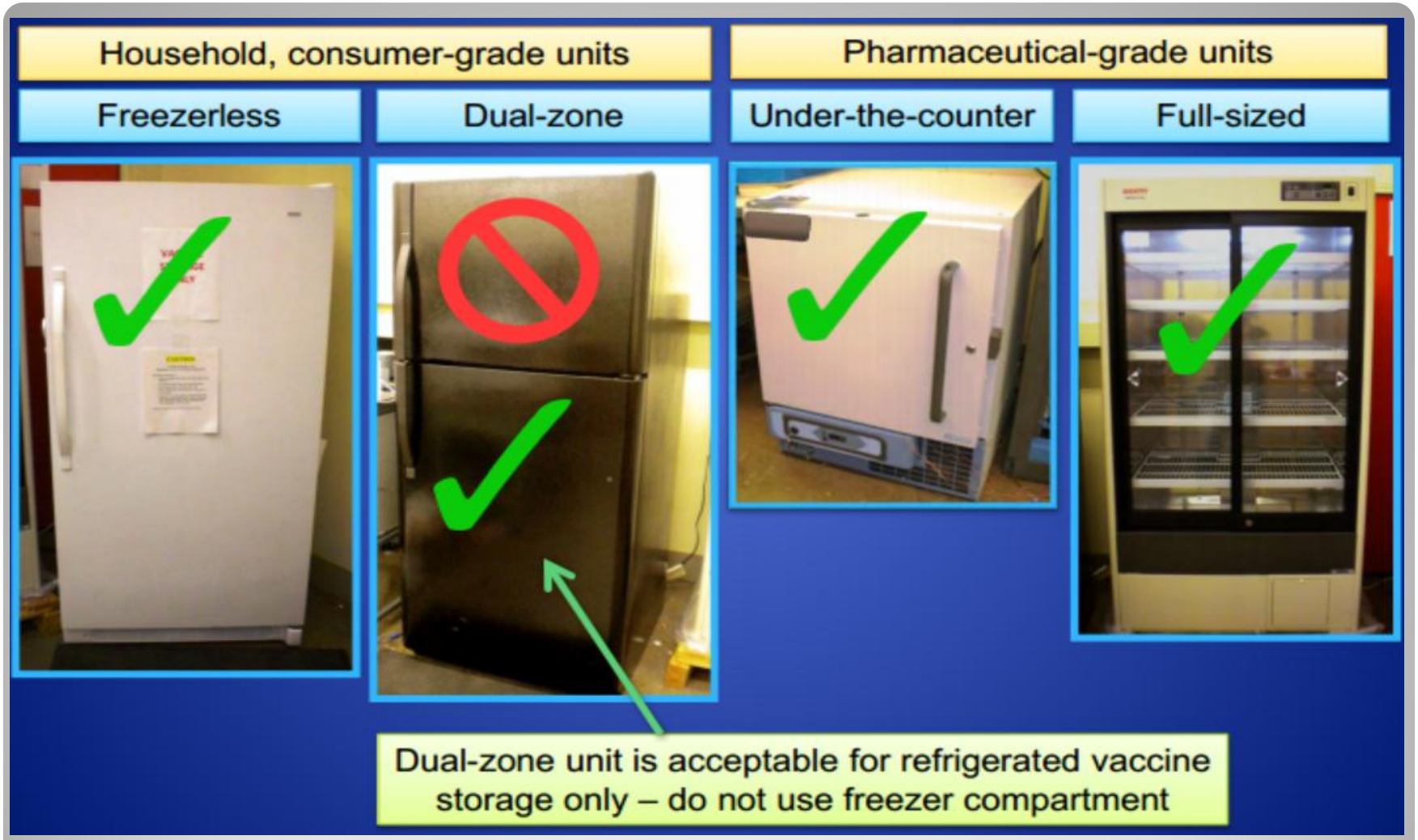
VFC Requirements:

- Use of water bottles and icepacks to help maintain temperatures during power outage or frequent door openings.
- Dorm Style units are no longer permitted for storage of any vaccine.

VFC Recommendations:

- CDC Recommends stand along refrigerators and freezers based on the National Institute of Standards and Technology (NIST)
  - Combination are an alternative- discontinue use of freezer if temperatures are not consistently in range.

Principle 2

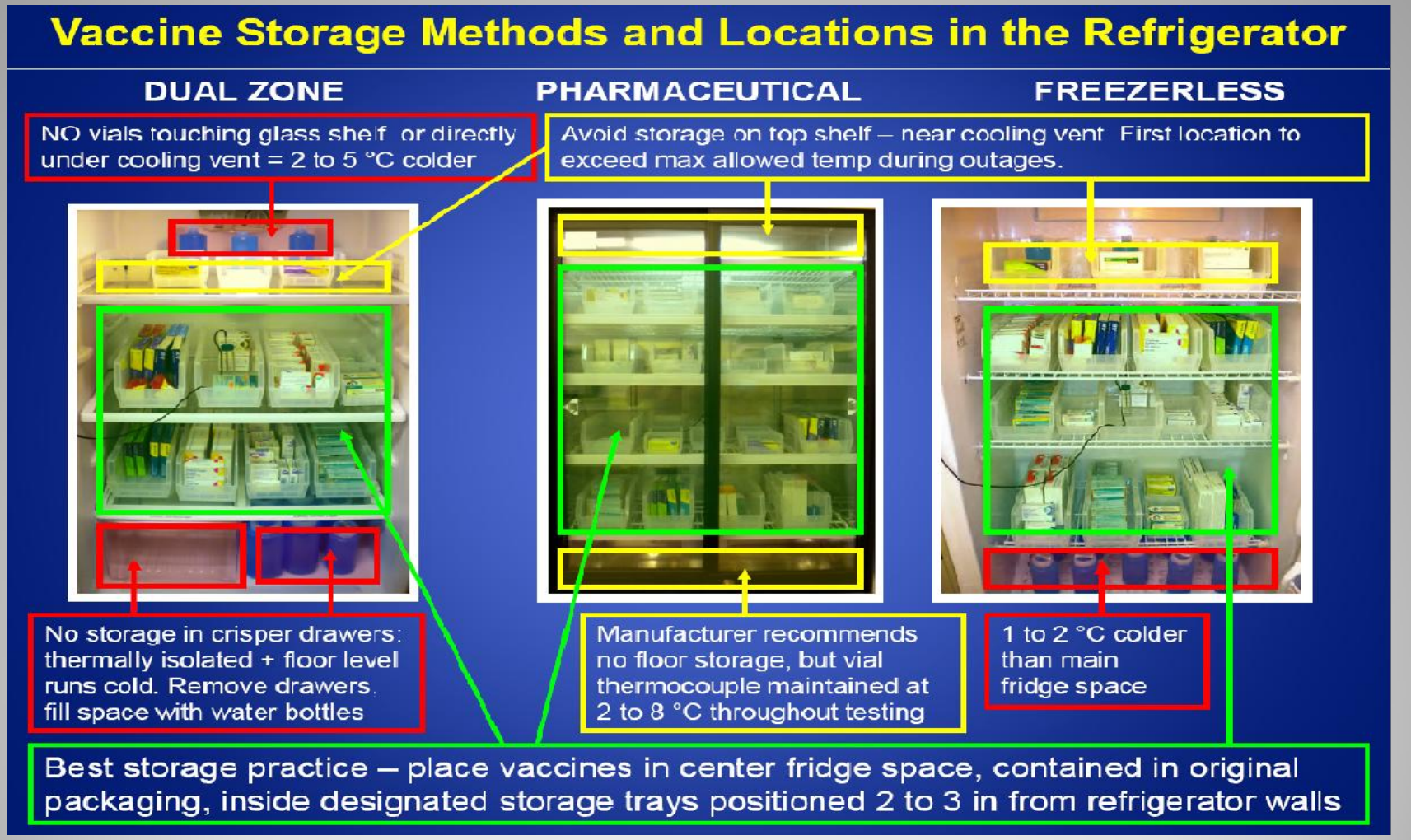


Vaccine storage Units

STORE VACCINES IN A TEMPERATURE STABLE LOCATION OF THE STORAGE UNIT

Principle 3

Vaccine Storage Methods and Locations in the Refrigerator



Vaccine Storage Units

Vaccine Placement

- *Stand Alone:*
  - Vaccine stored in the upper shelves of the unit experienced the quickest temperature increases.
  - The middle shelves of the unit demonstrated the most consistent temperatures.
  - Crisper drawers and floor temperatures- no consistency.
  - *In the top, vaccines experienced the quickest temperature increases during power outage.*

Vaccine Placement

- Pharmaceutical Grade:
  - Manufacturers do not recommend vaccine storage on bottom of unit.
  - Glass doors experience quickest temperature increase due to lack of insulation.

VFC Requirements:

- Store vaccines in the middle of the storage unit away from the coils, walls, floor and cold air vents.
- Vaccines should not be stored in the door as this part of the unit tends to be warmer than the main storage area.
- Store water bottles in the refrigerator and frozen packs in the freezer to provide thermal ballast for temperature stability. Put them in the door, floor, and close to the walls helps to keep vaccine away from those areas.

Principle 3

MONITOR VACCINE STORAGE UNIT TEMPEATURES

Principle 4

Temperature Monitoring

- Temperature ranges:
  - 35F to 46F (2C to 8C)
- Provider are required to manually document temperatures 2x daily– even if practice uses continuous monitoring system.
- NIST Certified thermometer
  - Must be glycol or glycerin encased probe– no ambient temperature thermometers.
  - Placed in central location in storage unit.

Temperature Monitoring

- *CDC recommends-* ***24 hour temperature monitoring***
- For best result, data loggers must have detachable probes.
- 15 minute increments.
- Downloadable with no over writes.

VFC Requirements:

- Use certified calibrated thermometers with a current certificate of calibration testing & traceability for areas where vaccine is stored.

VFC Recommendations

- CDC recommends a digital thermometer with a detachable biosafe glycol-encased probe (See CDC storage and handling toolkit for more details)

Principle 4

IMMEDIATELY UNPACK VACCINE DELIVERIES, EXAMINE AND STORE

Principle 5

- Always communicate with front desk!!
- When unpacking:
  - Examine cold indicator for proof that vaccine may have gone out of proper temperature ranges.
  - Always keep vaccine in original boxes.
  - For extra protection and better organization– Use storage trays.

Unpack, Examine, Store!!

- Things to check in at delivery:
  - Vaccine matches diluent
    - Only use vaccine appropriate diluent
  - Quantity
    - Check before accepting in Registry
  - Quality
    - Does it look weird?? Was it packed correctly?
  - Lot number/ Expiration Date

Once checked for accuracy, accept your order in the registry.

Unpack, Check, Store!!

VFC Requirements:

- Keeping vaccine in boxes and storage trays offered greater thermal protection to the vaccines especially in situations of power outage and frequent door opening.
- VFC requires that vaccine packages be opened immediately. Any problems should be reported to Immunization Branch as soon as possible.
- Providers should arrange for deliveries only when the vaccine coordinator or alternate will be available. Things to check in a delivery: Vaccine matches diluent, Appropriate quantity, Quality issue questions, Was vaccine packed properly.

Principle 5

REMOVE EXPIRED VACCINE FROM STORAGE UNIT

Principle 6

Expired Vaccine

- Identify soon to expire vaccine and diluents.
- Move vaccine with earliest expiration date to front of the unit and use it first.
- When expired, remove from unit and send to Immunization Branch.
- Use pre-paid mailing label to send vaccine back to proper location.

VFC Requirements:

- Provider maintain separate public/private stock records.
- Notify NCIP program of soon to expire vaccine
- Remove expired vaccine from storage unit.
- Return expired vaccine as directed by NCIP.
- Work with NCIP for transfer of soon to expire vaccine.
- Use vaccine with earliest date first.

Principle 6

PROVIDE MAXIMUM AT WORST TEMPERATURE WHEN CALLING IMMUNIZATION BRANCH ABOUT TEMPERATURE OUTAGE

Principle 7

Out of Range Temperature

- When calling the Immunization Branch, have the following information
  - Vaccines affected,
  - Longest possible time out of range,
  - Highest Temperature Reached,
  - Vaccine Lots and Expiration Dates,
  - Room temperature if unsure about highest temperature reached.
- Report Worst Case Scenario.

Out of Range Temperature

- Never assume vaccine isn’t viable.
- Never leave vaccines in non working unit.
- Mark Vaccine “do not use”.
- Return vaccines back to proper storage temperatures as soon as possible.
- Review Disaster Recovery Plan yearly for accuracy and document review.
- Mark viable vaccine to easily identify vaccines affected in excursion.

Out of Range Temperature

VFC Requirements:

- Providers should immediately report storage problems to Immunization Branch.
- Document Incident as well as corrective actions taken.
- Providers should have written protocols for reports and response.

- Providers should immediately report storage problem to immunization program.
- Document the incident as well as corrective action taken.
- Providers should have written protocols for report and response.
- Separate and label potentially compromised vaccine – so that it doesn't inadvertently get used.
- Store it under correct temperature – if this is not done, the clock keeps ticking on the excursion.
- Contact immunization program to determine viability of the vaccine.
- If wasted, remove from storage unit because it no longer needs to be kept under correct storage temperature.
- Correct the original problem.

Principle 7

USE UNITS THAT MAINTAIN CORRECT TEMPERATURES (EVEN FOR TEMPORARY STORAGE)

Principle 8

Transporting Vaccines

- Improper packing of vaccine can be as risky as storage unit failure.
- What is ok for transport may not be ok for temporary storage.
- Permanent and temporary storage units have the same requirements.

VFC Requirements:

- Providers should have an emergency plan that includes transport.
- Providers should have supplies to transport appropriately.
- Use a calibrated temperature monitoring device for any transport and temporary storage.
- If local transport is done frequently, use a portable refrigerator or freezer.
- If not using portable equipment, unpack vaccines after transport and store in refrigerator or freezer.

Principle 8

QUESTIONS???

Shirelle Everett
Shirelle.everett@dhhs.nc.gov
919-707-5574